

John E. Flaherty
Ravin R. Patel
McCARTER & ENGLISH LLP
Four Gateway Center
100 Mulberry St.
Newark, NJ 07102
Telephone: (973) 622-4444

*Attorneys for Plaintiffs Horizon Pharma
Ireland Limited, HZNP Limited and
Horizon Pharma USA, Inc.*

Dennis A. Bennett
GLOBAL PATENT GROUP, LLC
1005 North Warson Road, Suite 404
St. Louis, Missouri 63132
Telephone: (314) 812-8020

*Of Counsel for Plaintiffs Horizon
Pharma Ireland Limited, HZNP Limited
and Horizon Pharma USA, Inc.*

Robert F. Green
Christopher T. Griffith
Caryn C. Borg-Breen
Benjamin D. Witte
GREEN, GRIFFITH & BORG-BREEN LLP
NBC Tower, Suite 3100
455 North Cityfront Plaza Drive
Chicago, Illinois 60611
Telephone: (312) 883-8000

*Of Counsel for Plaintiffs Horizon Pharma
Ireland Limited, HZNP Limited and Horizon
Pharma USA, Inc.*

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

HORIZON PHARMA IRELAND LIMITED,
HZNP LIMITED and HORIZON PHARMA USA,
INC.,

Plaintiffs,

v.

ACTAVIS LABORATORIES UT, INC.,

Defendant.

C.A. No. 14-cv-7992-NLH-AMD
(Consolidated with C.A. Nos. 15-
5025, 15-6131, 15-6989)

Judge Noel L. Hillman

Magistrate Judge Ann Marie Donio

HORIZON PHARMA IRELAND LIMITED,
HZNP LIMITED and HORIZON PHARMA USA,
INC.,

Plaintiffs,

v.

AMNEAL PHARMACEUTICALS LLC,

Defendant.

C.A. No. 1:15-CV-3367-NLH-AMD
(Consolidated with C.A. Nos. 15-cv-
5024, -6132)

Judge Noel L. Hillman

Magistrate Judge Ann Marie Donio

PLAINTIFFS' OPENING CLAIM CONSTRUCTION BRIEF

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	THE PATENTS-IN-ISSUE	1
A.	The Current Consolidated Actions.....	1
B.	Background of the Horizon Patents	2
III.	AGREED UPON CLAIM CONSTRUCTION	4
IV.	THE LAW OF CLAIM CONSTRUCTION.....	8
A.	Legal Standards for Claim Construction	8
B.	The Person of Ordinary Skill in the Art (POSA).....	9
V.	CONSTRUCTION OF THE DISPUTED CLAIM TERMS	10
A.	“consisting essentially of”	10
B.	“ethanol”	12
C.	“the formulation degrades by less than 1% over 6 months”	18
D.	“the topical formulation produces less than 0.1% impurity A after 6 months at 25°C and 60% humidity”	22
E.	“said diclofenac sodium degrades by less than 0.04% over the course of 6 months”	23
F.	“topical diclofenac preparation”	23
G.	“the patient being informed to”	25
H.	“the patient carrying-out steps i-iii as informed”	26
I.	“providing information”	27
J.	“informing the patient to”	28
K.	“a greater drying rate”	28
L.	“said drying rate results in a residue of at most 50% of a starting amount after 24 hours”	33
M.	“as determined by a Franz cell procedure at finite or infinite dosing”	35
N.	“hydroxypropyl-cellulose (HY119)”	38
VI.	CONCLUSION	39

TABLE OF AUTHORITIES

Cases

<i>ACTV, Inc. v. Walt Disney Co.</i> , 346 F.3d 1082 (Fed. Cir. 2003)	8
<i>CollegeNet, Inc. v. ApplyYourself, Inc.</i> , 418 F.3d 1225 (Fed. Cir. 2005)	11
<i>Comark Communication, Inc. v. Harris Corp.</i> , 156 F.3d 1182 (Fed. Cir. 1998)	9
<i>Conoco, Inc. v. Energy & Env'tl. Int'l, L.C.</i> , 460 F.3d 1349 (Fed. Cir. 2006)	11
<i>Datamize LLC v. Plumtree Software, Inc.</i> , 417 F.3d 1342 (Fed. Cir. 2005)	passim
<i>Depomed, Inc. v. Sun Pharma Global FZE</i> , Civil Action No. 11-3553 JAP, 2012 WL 3201962 (D.N.J. Aug. 3, 2012)	11
<i>Exxon Res. & Eng'g Co. v. United States</i> , 265 F.3d 1371 (Fed Cir. 2001)	passim
<i>Haemonetics Corp. v. Baxter Healthcare Corp.</i> , 607 F.3d 776, 783 (Fed. Cir. 2010).....	30
<i>In re Flonase Antitrust Litig.</i> , 798 F. Supp. 2d 619 (E.D. Pa. 2011)	14
<i>Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.</i> , 381 F.3d 1111 (Fed. Cir. 2004)	8, 9
<i>Interactive Gift Express, Inc. v. Compuserve Inc.</i> , 256 F.3d 1323 (Fed. Cir. 2001)	8
<i>Markman v. Westview Instruments, Inc.</i> , 517 U.S. 370 (1996).....	8
<i>Microsoft Corp. v. i4i Ltd. P'ship</i> , 131 S. Ct. 2238 (2011)	29
<i>Nautilus, Inc. v. Biosig Instruments, Inc.</i> , 134 S. Ct. 2120 (2014)	17, 29, 30
<i>Phillips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005) (en banc)	8, 9
<i>PPG Indus. v. Guardian Indus. Corp.</i> , 156 F.3d 1351 (Fed. Cir. 1998)	11, 12
<i>Renishaw PLC v. Marposs Societa' per Azioni</i> , 158 F.3d 1243 (Fed. Cir. 1998)	9
<i>Teva Pharm. USA, Inc. v. Sandoz, Inc.</i> , 789 F.3d 1335 (Fed. Cir. 2015)	30

<i>Texas Instruments Inc. v. U.S. International Trade Commission</i> , 988 F.2d 1165 (Fed. Cir. 1993)	8
<i>Unique Concepts, Inc. v. Brown</i> , 939 F.2d 1558 (Fed. Cir. 1991)	8
<i>Vitronics Corp. v. Conceptoronic, Inc.</i> , 90 F.3d 1576 (Fed. Cir. 1996)	8, 9

I. INTRODUCTION

The Horizon patents-in-issue describe and claim inventions covering PENNSAID® 2% – the first FDA-approved twice-daily topical diclofenac sodium formulation for the treatment of the pain of osteoarthritis (“OA”) of the knee(s). The unique PENNSAID® 2% formulation and related methods described in the Horizon patent claims provide not only an alternative to conventional therapies, such as oral NSAIDS, but several important advantages to patients who suffer from the pain of OA.

Horizon is the current owner and assignee of the patents-in-issue, and of the PENNSAID® 2% New Drug Application (“NDA”); all rights therein were acquired from third parties. Since Horizon’s launch of PENNSAID® 2% in early 2015, sales targets have exceeded expectations, with year-to-date sales of PENNSAID® 2% reaching about \$314 million through September of 2015.

II. THE PATENTS-IN-ISSUE

A. The Current Consolidated Actions

Horizon has filed several Hatch-Waxman actions in this judicial district alleging patent infringement against generic companies seeking to market copies of Horizon’s successful PENNSAID® 2% formulation prior to the expiration of Horizon’s patents. In accordance with the relevant scheduling orders, this brief addresses claim construction issues relevant to the actions consolidated to date against two generic companies, *i.e.*, Actavis Laboratories UT, Inc. (“Actavis”) and Amneal Pharmaceuticals LLC (“Amneal”).

Horizon brought the Actavis actions in response to Actavis’ assertion that the generic copy of PENNSAID® 2% described in Actavis’ Abbreviated New Drug Application No. 207238 (“ANDA”), if approved by the FDA, would not infringe any valid and enforceable Horizon

patent, and Actavis' further assertion that it intends to market its FDA-approved generic copy of PENNSAID® 2% prior to the expiration of the Horizon patents.

Horizon timely brought the first of the consolidated actions for patent infringement against Actavis on December 23, 2014. (*See* 14-cv-7992, ECF No. 1.) The automatic 30-month stay relative to Actavis' ANDA currently expires on May 14, 2017.

Similarly, Horizon brought the Amneal actions in response to Amneal's assertion that the generic copy of PENNSAID® 2% described in Amneal's Abbreviated New Drug Application No. 208198, if approved by the FDA, would not infringe any valid and enforceable Horizon patent, and Amneal's assertion that it intends to market its FDA-approved generic copy of PENNSAID® 2% prior to the expiration of the Horizon patents.

Horizon timely brought the first of the consolidated actions for patent infringement against Amneal on May 15, 2015. (*See* 15-cv-3367, ECF No. 1.) The automatic 30-month stay relative to Amneal's ANDA currently expires on October 2, 2017.

In a letter to the Court dated October 29, 2015, defendants Actavis and Amneal (collectively "Defendants") notified the Court that they will file one joint opening *Markman* brief. In correspondence dated October 28, 2015, Amneal confirmed that it will adopt each of Actavis' proposed constructions for those terms upon which the parties disagree and/or the agreed upon constructions. Accordingly, Horizon submits one opening *Markman* brief addressing the constructions disputed in the Actavis and Amneal consolidated actions.

B. Background of the Horizon Patents

There are nine Horizon patents asserted against the Defendants in the consolidated

actions: U.S. Patent Nos. 8,252,838 (“the ’838 patent,” Exh. 1¹), 8,563,613 (“the ’613 patent,” Exh. 2), 8,871,809 (“the ’809 patent,” Exh. 3), 9,066,913 (“the ’913 patent,” Exh. 4), 9,101,591 (“the ’591 patent,” Exh. 5), 8,546,450 (“the ’450 patent,” Exh. 6), 8,217,078 (“the ’078 patent,” Exh. 7), 8,618,164 (“the ’164 patent,” Exh. 8) and 9,132,110 (“the ’110 patent,” Exh. 9), although the patents may be segregated into groups in accordance with their related specifications.²

The first group of Horizon patents, *i.e.*, the ’838, ’613, ’809, ’913 and ’591 patents, share substantially identical specifications and claim priority to the same provisional application filed on October 17, 2006. The inventors, as set forth in these Horizon patents, recognized a significant unmet need for, *inter alia*, topical OA pain treatments suitable for chronic use that will deliver the active agent to the underlying tissue in sufficient concentration, while reducing or minimizing skin irritation and while providing a formulation and dosage that encourages patient compliance. (Exh. 1, ’838 patent at col. 4, ll. 2-18.) These same patents describe how the present invention surprisingly overcomes various disadvantages of the prior art. For example, and among other unexpected results, the invention provides diclofenac sodium formulations for the treatment of OA that exhibit better drying time, higher viscosity, increased transdermal flux, a low level of impurities and greater pharmacokinetic absorption *in vivo* when compared to previously described compositions. (Exh. 1, ’838 patent at col. 4, ll. 22-39.)

The second group of Horizon patents, *i.e.*, the ’450, ’078, ’164 and ’110 patents, also

¹ “Exh. ___” refers to the Exhibits attached to the Declaration of Benjamin Witte in Support of Plaintiffs’ Opening Claim Construction Brief.

² The specifications of the ’838, ’613, ’809, ’913 and ’591 patents are substantially identical; references herein will be made to the specification of the ’838 patent. Similarly, the specifications of the ’450, ’078, ’164 and ’110 patents are substantially identical; references will be made to the specification of the ’450 patent or ’110 patent.

share substantially identical specifications, and claim priority to the same provisional application filed on October 31, 2012. The inventors, as set forth in these Horizon patents, recognized a need for, *inter alia*, improved methods of dosing topical diclofenac formulations, and developed methods of providing users and prescribers with information regarding the attributes and desired therapeutic effects of the inventive topical formulations, as well as instructions their use in conjunction with other topical agents. (Exh. 6, '450 patent, col. 3, l. 65 to col. 4, l. 3.)³

III. AGREED UPON CLAIM CONSTRUCTION

In accordance with Scheduling Order No. 2 entered by this Court in 14-cv-7992 (ECF No. 43) and the Local Patent Rules, the parties have exchanged terms appearing in the Horizon patent claims that each party contends requires construction, and conferred to determine if disputes concerning their construction could be narrowed. As a result of cooperation among the parties, agreement was reached on the construction of several claim terms in the Horizon patents, as set forth in the following chart:

Claim Term	Claims	Agreed Upon Construction
"topical formulation"	'838 patent: claims 1-19, 21-24, 27-33, 35-43, 46-52, 55-69 '613 patent: claims 1-5, 9-19, 22-24 '809 patent: claims 1-6, 10-15, 17 '913 patent: claims 1-12 '591 patent: claims 1-3, 5, 6, 8-15, 17 and 19-25	A formulation that can be applied to skin or a mucosa.

³ Additional advantages of the claimed inventions relative to the prior art are set forth in Horizon's contentions served in the various actions pending in this judicial district, and will be further identified and developed as discovery progresses in each of the consolidated actions.

Claim Term	Claims	Agreed Upon Construction
“wherein transdermal flux is measured at a time of 14 hours, or 18 hours, or 28 hours, or 31 hours or 40 hours or 42 hours after placing the formulations in the Franz cell”	’838 patent: claims 15, 30	Transdermal flux meets the requirements of the claim at one or more of the specified intervals after placement in a Franz cell
“combination therapy”	’450 patent: claims 1-5, 7, 9	Concomitant treatment of a medical condition with more than one substance
“the patient is treated for breakthrough knee pain”	’450 patent: claim 3	Plain and ordinary meaning
“a second medication consisting of a topical medication, which is other than said first medication [and is selected from the group consisting of an NSAID, tretinoin, minoxidil, a corticosteroid] [and comprises a corticosteroid]”	’078 patent: claims 1, 2, 5, 9, 11 and 14 ’110 patent, claims 1-28	The second medication consists of a topical medication, which is other than said first medication [and is selected from the group consisting of a topical NSAID, topical tretinoin, topical minoxidil, a topical corticosteroid] [and comprises a topical corticosteroid]
“a second prescription medication consisting of a topical medication other than said first medication” “[the subsequently applied] second medication consisting of a topical medication other than said first medication”	’164 patent: claims 1, 2 and 5-8	The second medication comprises a topical medication, which is sold by prescription only (<i>i.e.</i> , not sold over the counter), other than the first medication
“insect repellant”	’450 patent: claims 10-11, 14-20 ’110 patent: claims 1-13, 18-21 and 24-28	A topical substance commonly marketed for repelling insects
“wherein the topical diclofenac preparation comprises a	’078 patent: claims 1, 2, 5, 9, 11, 14	An amount of diclofenac or its pharmaceutically acceptable salts thereof or its free acid form in a preparation which, when applied

Claim Term	Claims	Agreed Upon Construction
therapeutically effective amount of diclofenac”	’164 patent: claims 1, 2, 5-8 ’110 patent: claims 1-28	onto the skin, is sufficient to induce a desired biological, pharmaceutical or therapeutic result involving the reduction or prevention of pain
“a viscosity of 500-5000 centipoise”	’838 patent, claims 1-19, 21-24, 27-33, 35-43, 46-52, 55-69 ’613 patent: claims 1-5, 9-19, 22-24 ’809 patent: claims 1-6, 10-15, 17 ’913 patent: claims 1-12 ’591 patent: claims 1-3, 5, 6, 8-15, 17 and 19-25	A topical formulation having a viscosity of [500-5000] centipoise when measured at 22°C using a Brookfield DV-III Ultra programmable Rheometer with LV Spindle #31 at 10 rpm
“published material”	’110 patent: claims 10-11, 18-19, 26	Printed, audio, visual, or electronic medium, for example a flyer, an advertisement, a product insert, printed labeling, an internet web site, an internet web page, an internet pop-up window, a radio or television broadcast, a compact disk, a DVD, a podcast, an audio recording, or other recording or electronic medium
“a medium providing information”	’110 patent: claims 12-13, 20-21, 27-28	Printed, audio, visual, or electronic medium, for example a flyer, an advertisement, a product insert, printed labeling, an internet web site, an internet web page, an internet pop-up window, a radio or television broadcast, a compact disk, a DVD, a podcast, an audio recording, or other recording or electronic medium providing instructions.
“written instructions”	’110 patent: claims 14-17, 22-25	Plain and ordinary meaning

There remain, however, eight terms to construe in the Horizon patents:

- “consisting essentially of” (identified by Defendants only);

- “ethanol”;
- the related terms “the formulation degrades [by] less than 1% over 6 months,”⁴ “the topical formulation produces less than 0.1% impurity A after 6 months at 25°C and 60% humidity” and “said diclofenac sodium degrades by less than 0.04% over the course of 6 months”;
- “topical diclofenac preparation”;
- the related terms “the patient being informed to,” “the patient carrying-out steps i-iii as informed,” “providing information” and “informing the patient to.”
- The related terms “a greater drying rate” and “said drying rate results in a residue of at most 50% of a starting amount after 24 hours”;
- “as determined by a Franz cell procedure at finite or infinite dosing”;
- “Hydroxypropyl-cellulose (HY 119)”

Defendants’ claim construction positions, set forth in limited detail *infra*, also make cursory assertions that certain of these terms (*i.e.*, “consisting essentially of”—a transitional phrase—, “ethanol,” and the terms relative to degradation, drying rate and flux) are indefinite under 35 U.S.C. § 112. Yet at the same time, with respect to each of these purportedly indefinite terms (except the Franz cell procedure term), Defendants provide a construction—thereby undercutting Defendants’ indefiniteness position relative to each of these terms.

Horizon reserves the right to address these indefiniteness assertions at the appropriate time (when more fully presented). If the Court is inclined to address these issues now, Horizon submits that, because Defendants provided a construction for these terms, the Court should find the terms not indefinite and proceed to construe them—albeit by adopting Horizon’s proposals.

⁴ Certain asserted claims, *i.e.*, claims 10, 11 and 19 of the ’591 patent, contain the phrase “the formulation degrades at less than 1% over 6 months.”

IV. THE LAW OF CLAIM CONSTRUCTION

A. Legal Standards for Claim Construction

Claim construction “is a question of law, to be determined by the court.” *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 384 (1996). The Court must decide the meaning of the claim terms or phrases as a person of ordinary skill in the art would understand them at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc).

In construing the claims, a court should begin first with the intrinsic evidence—*i.e.*, the claims, the specification, and the prosecution history. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). The intrinsic record provides the best evidence of how disputed claim terms should be construed. *Id.* However, “[a]ll intrinsic evidence is not equal.” *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001). As such, “a claim construction analysis must begin and remain centered on the claim language itself, for that is the language the patentee has chosen to ‘particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.’” *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004) (quoting 35 U.S.C. § 112, ¶ 2) (omissions in original). Indeed, “the claims themselves provide substantial guidance as to the meaning of particular claim terms,” and claim language should be construed in the context of and consistently with surrounding words in the claim. *Phillips*, 415 F.3d at 1314; *see also ACTV, Inc. v. Walt Disney Co.*, 346 F.3d 1082, 1088 (Fed. Cir. 2003) (“[T]he context of the surrounding words of the claim also must be considered in determining the ordinary and customary meaning of those terms.”). In that context, every word has meaning; one of the basic tenets of claim construction prohibits viewing any claim language as superfluous. *See, e.g., Tex. Instruments Inc. v. U.S. Int’l Trade Comm’n*, 988 F.2d 1165, 1171 (Fed. Cir. 1993); *Unique Concepts, Inc. v. Brown*, 939 F.2d 1558, 1562 (Fed. Cir. 1991) (“All the limitations of a claim

must be considered meaningful . . .”).

The specification may also provide context for the meaning of the claim. In fact, the specification “is the single best guide to the meaning of a disputed term.” *Vitronics*, 90 F.3d at 1582. While the specification may provide a context for the claims, the Federal Circuit has cautioned that “a court may not read a limitation into a claim from the specification.” *Innova*, 381 F.3d at 1116-17. Additionally, a court may not limit the claims to merely one preferred embodiment of the claimed invention, absent some express disclaimer made by the patentee during prosecution. *See, e.g., Comark Commc’ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1187 (Fed. Cir. 1998).

The prosecution history also may be of significance when construing claims. *Vitronics Corp.*, 90 F.3d at 1582. For example, “the prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention.” *Phillips*, 415 F.3d at 1317.

Extrinsic evidence, *i.e.*, treatises, technical references, and expert testimony, may be useful in providing guidance on the context of technical terms and the ordinary and customary meaning of a term to a person of ordinary skill in the art. *Phillips*, 415 F.3d at 1314. While these may be considered by a court, such sources may not be used “to contradict claim meaning that is unambiguous in light of the intrinsic evidence.” *Id.* at 1324. Ultimately, “[t]he construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.” *Id.* at 1316 (quoting *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998)).

B. The Person of Ordinary Skill in the Art (POSA)

The patents-in-suit generally relate to topical drug formulations and methods of using those formulations for the treatment of the pain of osteoarthritis. As a preliminary description,

and reserving the right to amend this description of a person of ordinary skill in the art (“POSA”) as part of expert discovery, a POSA relative to the patents-in-suit is: (i) a person holding a Bachelor’s degree in pharmacy or chemistry or a related discipline and, in addition, an advanced degree in a related field (or, alternatively, an equivalent number of years of work experience in the pharmaceutical field) as well as a few years of experience in the development of topical formulations, with access to a clinician with several years of experience in treating patients using topical formulations that would understand the clinical considerations relevant to topical formulations, or (ii) a clinician with several years of experience in treating patients using topical formulations that would understand the clinical considerations relevant to topical formulations, with access to a person holding a Bachelor’s degree in pharmacy or chemistry or a related discipline and, in addition, an advanced degree in a related field (or, alternatively, an equivalent number of years of work experience in the pharmaceutical field) as well as a few years of experience in the development of topical formulations. (*See* Walters Decl. ¶ 20.)

V. CONSTRUCTION OF THE DISPUTED CLAIM TERMS

A. “consisting essentially of”

Disputed Claim Term	Claim(s)	Horizon’s Proposed Construction	Defendants’ Proposed Construction
“consisting essentially of”	’838 patent: claims 1-19, 21-24, 27-33, 35-43, 46-52, 55-61 ’591 patent: claims 12-15, 17, 19, 24 and 25	Legal issue – no construction needed in Markman phase; also, meaning cannot be ascertained in the absence of proper context	Comprising; if interpreted otherwise, the claims are invalid as indefinite and/or lacking adequate written description under 35 U.S.C. § 112.

Defendants (only) desire to construe the term “consisting essentially of.” This term is a transitional phrase—traditionally used in patent claims as intermediary language between the preamble and the body of a claim.

There exist several transitional phrases, and decades of case law has developed around these phrases, and provided meaning thereto. The transition phrase “comprising,” for example, has been found by the courts to be inclusive, or open-ended, and as such does not exclude any unrecited claim elements. *See CollegeNet, Inc. v. ApplyYourself, Inc.*, 418 F.3d 1225, 1235 (Fed. Cir. 2005). In contrast, the transitional phrase “consisting of” has been found to exclude any element, step, or ingredient not specified in the claim. *Conoco, Inc. v. Energy & Env'tl. Int'l, L.C.*, 460 F.3d 1349, 1360 (Fed. Cir. 2006).

A corollary to “consisting of” is “consisting essentially of.” “By using the term ‘consisting essentially of,’ the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention.” *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998). The determination of whether an unlisted ingredient materially affects the basic and novel properties of the invention is a factual, context specific question. *Id.* at 1357. (With respect to a “consisting essentially of” claim, “[t]he court properly left it to the jury to determine whether the amounts of iron sulfide in SMG glass have a material effect on the basic and novel characteristics of the glass.”)

Horizon contends at the outset that “consisting essentially of” is a legal term which has an accepted meaning and, as such, need not be construed in the *Markman* phase. *Depomed, Inc. v. Sun Pharma Global FZE*, Civil Action No. 11-3553 JAP, 2012 WL 3201962, at *13 (D.N.J. Aug. 3, 2012) (“The Court agrees with Plaintiffs that this term does not require independent construction. First, ‘consisting essentially of’ has an accepted meaning in patent law and does not need further definition.”)

Separate and apart from the foregoing, Defendants’ proposed construction fails for at least two additional reasons. Ignoring decades of precedent, Defendants ask that the common understanding of “consisting essentially of” be discarded, and that the meaning of a different transitional phrase—“comprising”—be adopted in its place. In addition, Defendants argue in essence that, if the Court disagrees with its proposed construction, then “consisting essentially of” should be found indefinite – which ignores decades of Court decisions which set forth the well-understood meaning of this transitional phrase.

While Horizon submits that it is premature to construe “consisting essentially of” at the present time, if the Court is inclined to do so, Horizon submits that “consisting essentially of” should be construed in accordance with decades of precedent, *i.e.*, “the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention.” *PPG Indus.*, 156 F.3d at 1354. In any event, there is no good reason to conclude that this term is indefinite under Section 112.

B. “ethanol”

Disputed Claim Term	Claim(s)	Horizon’s Proposed Construction	Defendants’ Proposed Construction
“ethanol”	<p>’838 patent: claims 1-19, 21-24, 27-33, 35-43, 46-52, 55-69</p> <p>’613 patent: claims 1-5, 9-19, 22-24</p> <p>’809 patent: claims 2, 4-6, 10-15</p> <p>’913 patent: claims 1-12</p>	A liquid containing between 92.3-93.8 % w/w or 94.9-96.0 % v/v C ₂ H ₅ OH	“Pure ethanol,” <i>i.e.</i> , C ₂ H ₅ OH, or “100% ethanol”; alternatively, this term is indefinite.

	'591 patent: claims 1-3, 5, 6, 8-15, 17 and 19-25		
	'110 patent: claims 4, 17		

Horizon submits that the term “ethanol” should be construed as a POSA would have understood this term at the time of the invention—in view of the claims, specification and prosecution history: A liquid containing between 92.3-93.8 % w/w or 94.9-96.0 % v/v C₂H₅OH.

In contrast, Defendants ask this Court to rewrite the term, adding adjectives (modifiers) that are found nowhere in the intrinsic evidence, *i.e.*, “pure” [ethanol] or “100%” [ethanol] and, further, propose two constructions for this term. Absent adoption of one of their two proposed constructions, Defendants offer a third option, asking the Court to declare the term to be indefinite. While Defendants offer three unsupported options, Horizon’s construction is the only one that is consistent with the plain meaning of the term, and does not include any improper modification. The Court is thus urged to adopt Horizon’s construction, and reject Defendants’ two constructions (as well as Defendants’ “alternative” indefiniteness argument).

The specifications and claims of the relevant patents consistently refer to “ethanol,” without any other modifiers. (*See, e.g.*, Exh. 1, ’838 patent, col. 4, l. 40 to col. 5, l. 7; col. 5, ll. 16-23, 29-45; col. 7, l. 66 to col. 8, l. 4.) The one place that an additional modifier is used in connection with ethanol is in Table 1, wherein the specifications identify “Ethanol (USP)” in the list of materials used in the examples. (Exh. 1, ’838 patent, col. 12, ll. 18-19.) Nowhere in the claims, specifications or file histories of the relevant patents can Defendants’ constructions—“pure ethanol” or “100% ethanol”—be found.

“Ethanol” is a familiar term in the art. Horizon’s construction comports with the general understanding a POSA would have had of the term “ethanol” as of the time of the invention.

(*See* Walters Decl. ¶¶ 24-25.)⁵ A POSA would have understood “ethanol” to refer to a liquid containing between 92.3-93.8 % w/w or 94.9-96.0 % v/v C₂H₅OH. (*See* Walters Decl. ¶ 24.) This is so because it would have been commonly understood by a POSA that “ethanol,” absent any modifier, is a liquid containing between 92.3-93.8 % w/w or 94.9-96.0 % v/v C₂H₅OH, and that ethanol that is 100% ethanol would have been referred to as “dehydrated alcohol,” “200 proof alcohol,” or “absolute alcohol.” A POSA would have understood that there must be additional language modifying “ethanol” or “alcohol” if one were to interpret the term “ethanol” alone to mean “pure ethanol” or “100% ethanol.” (*See* Walters Decl. ¶ 26.)

Further, a POSA would have understood that “Ethanol (USP)” refers to a liquid containing between 92.3-93.8 % w/w or 94.9-96.0 % v/v C₂H₅OH. (*See* Walters Decl. ¶ 25.) As set forth *infra*, the United States Pharmacopoeia (“USP”), a compendium relied upon by the FDA when issuing its own pharmaceutical standards,⁶ includes separate entries for “alcohol,” which at the time of the invention would have been understood by a POSA in the context of the Horizon patents to be synonymous with ethanol. (*See* Walters Decl. ¶ 29.)

Horizon’s construction comports with the literature definitions of “ethanol” or “alcohol.” The following references, cited by both Horizon and Defendants, make it clear that what Defendants call “pure ethanol” or “100% ethanol,” is consistently referred to with an added modifier, such as “dehydrated” or “pure 100%”—and is not what a POSA would have understood to be the meaning of the term “ethanol” alone (absent a modifier).

⁵ “Walters Decl. ¶__.” refers to the cited paragraph of the Declaration of Dr. Kenneth A. Walters on Claim Construction, filed herewith.

⁶ *See* Walters Decl. ¶ 30; *see also In re Flonase Antitrust Litig.*, 798 F. Supp. 2d 619, 623 (E.D. Pa. 2011) (“The FDA regularly consults USP standards as a reference point when issuing its own pharmaceutical standards.”)

- United States Pharmacopeia 26 (Jan. 1, 2003), contains two separate entries, one for “Alcohol” and another one for “Dehydrated Alcohol” (Exh. 10, HZNPENN_00035293-294). The entry for “Alcohol” in the 2003 USP (USP dated prior to the filing date of the Horizon patents) defines “Alcohol” as containing “not less than 92.3 percent and not more than 93.8 percent, by weight, corresponding to not less than 94.9 percent and not more than 96.0 percent, by volume, at 15.56°, of C₂H₅OH,” and “Dehydrated Alcohol” as containing “not less than 99.2 percent, by weight, corresponding to not less than 99.5 percent, by volume, at 15.56°, of C₂H₅OH.”
- United States Pharmacopeia 29 (Jan. 1, 2006), contains two separate entries, one for Alcohol (Exh. 11, HZNPENN_0038256-261 at HZNPENN_00038258-259) and another one for Dehydrated Alcohol (Exh. 11, at HZNPENN_00038260-261). The 2006 USP (dated in or about the time of the Horizon patents) is consistent with the 2003 USP entry. It defines “Alcohol” as containing “not less than 92.3 percent and not more than 93.8 percent, by weight, corresponding to not less than 94.9 percent and not more than 96.0 percent, by volume, at 15.56°, of C₂H₅OH,” and “Dehydrated Alcohol” as containing “not less than 99.2 percent, by weight, corresponding to not less than 99.5 percent, by volume, at 15.56°, of C₂H₅OH.
- Spectrum Chemical Webpages (3) (2015) (Exh. 12, HZNPENN_00035289, -297, -298) contains two separate catalog entries, one for “Alcohol, 190 Proof, USP” and another one for “Dehydrated Alcohol, 200 Proof, Undenatured, USP.” These webpages, from the company identified as the source of “ethanol” in Table 1 of the Horizon patents, like the USP, supports the requirement of a modifier (e.g., “dehydrated alcohol, 200 Proof,

Undenatured, USP”) if one desires to convey a meaning other than 190 Proof (95%) ethanol.

- Hawley’s Condensed Chemical Dictionary (1987), contains an entry for “ethanol” that states “See ethyl alcohol” (Exh. 13, HZN PENN_00035309-310 at -309) and the entry for “ethyl alcohol” describes separately the properties of “pure 100% absolute alcohol (dehydrated)” and “USP grade,” defining “USP grade” as “95% by volume” (Exh. 13, at HZN PENN_00035310). Hawley’s also confirms a distinction between “pure 100% absolute alcohol” and “USP grade,” and defines USP grade consistent with Horizon’s construction—95% ethanol by volume.

Defendants cite to three additional references, in addition to the foregoing references cited by all parties, allegedly in support of its construction of the term “ethanol.” However, these references also support Horizon’s construction.

- ’838 patent file history, Desai Declaration, Exh. 14, ACT-PENN0003145-50, particularly ACT-PENN0003147-50, ¶¶ 13-15. This citation contains several references to “ethanol,” without any other modifiers – once again, this document does not in any manner explicitly or implicitly suggest that “ethanol” should be limited to “pure ethanol” or “100% ethanol.”
- Handbook of Pharmaceutical Excipients, at xx-xxi, 18-20, (Raymond C. Rowe et al. eds., 5th ed. 2006) Exh. 15, ACT-PENN0014600-08, particularly ACT-PENN0014604-08. This reference contains an entry for “Alcohol” that states in “the USP 28, the term ‘dehydrated alcohol’ refers to ethanol $\geq 99.5\%$ v/v. The term ‘alcohol’ *without the other qualification* refers to ethanol 94.9-96.0% v/v.” (Exh. 15, at ACT-PENN0014606) (emphasis added) This reference also states that the specification for “alcohol” found in

the USP contains approx. 95% v/v C₂H₅OH, and is the same as that found in the European Pharmacopeia and the Japanese Pharmacopeia. *Id.* Furthermore, included in the definition of “alcohol” there is a section entitled “Related Substances” where it defines “Dehydrated alcohol” as ethanol $\geq 99.5\%$ v/v. (Exh. 15, at ACT-PENN0014607)

Defendants strain to advance a construction defining ethanol as found in the claims, specification and prosecution history as anything other than a liquid containing between 92.3-93.8 % w/w or 94.9-96.0 % v/v C₂H₅OH, proposing instead that it somehow means “pure ethanol” or “100% ethanol.” Defendants’ proposed construction is not in accord with the ordinary meaning of the claim term or the description of the inventions in the specification and prosecution history. “Ethanol” was not a term unknown at the time of the patents. (*See, e.g.,* Walters Decl. ¶ 25.) Defendants’ construction as “pure ethanol” or “100% ethanol” is conspicuously absent from the specification and prosecution history. Defendants’ attempt to redraft the claims in an effort to generate a non-infringement argument, which, at the end of the day is futile, should be rejected.

While Horizon contends that an assessment of the issue of indefiniteness should be deferred until expert discovery is completed, there is reason at present to dismiss Defendants’ indefiniteness argument at this stage of the case. The foregoing evidence demonstrates that “ethanol” is not indefinite – it is a liquid containing between 92.3-93.8 % w/w or 94.9-96.0 % v/v C₂H₅OH. “[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014). A POSA would understand that, in the context of the dermal formulations described in the patents, “ethanol” would refer to a liquid containing

between 92.3-93.8 % w/w or 94.9-96.0 % v/v C₂H₅OH and not the more expensive, anhydrous, “pure ethanol” or “100% ethanol” alternative. (*See* Walters Decl. ¶ 37.) Thus, evidence presented by Defendants in support of their indefiniteness assertion falls far short of meeting the heavy “clear and convincing” burden required to demonstrate indefiniteness.

C. “the formulation degrades by less than 1% over 6 months”

Disputed Claim Term	Claim(s)	Horizon’s Proposed Construction	Defendants’ Proposed Construction
“the formulation degrades by less than 1% over 6 months”	’613 patent: claims 1-5, 9-19, 22-24 ’591 patent: claims 10, 11 and 19	Less than 1% of Impurity A (USP Diclofenac Related Compound A RS) present in a formulation sample after the sample was maintained at 25°C and 60% humidity for 6 months	This term is indefinite because it does not inform a person of ordinary skill with reasonable certainty of what is claimed. If construed, the term should be given its plain and ordinary meaning.

Horizon submits that this term, read in light of the specifications and the prosecution history, informs a POSA about the scope of the invention, is definite, and should be construed as meaning “less than 1% of Impurity A (USP Diclofenac Related Compound A RS) present in a formulation sample after the sample was maintained at 25°C and 60% humidity for 6 months.”

Horizon construes this and its related phrases consistent with the temperature, humidity conditions and testing protocol provided in the specifications of the Horizon patents. These parameters would provide a POSA with clear guidance to determine whether a formulation meets the degradation limitations of the claim.

Defendants allege that this term is indefinite, providing in the alternative that the term should be given its plain and ordinary meaning. The term is not indefinite. The specifications of the Horizon patents teach how to make and use the claimed formulations. (*See, e.g.*, Exh. 1, ’838

patent at col. 10, l. 49 - col. 11, l. 5.) The specifications teach specific examples of the claimed formulation. (*See, e.g.*, Exh. 1, '838 patent at Table 5 – Table 10, Table 12 (Formulation F/14/2); *see also* Exh. 1, '838 patent at col. 5, ll. 29-45.) The specifications also teach the conditions and procedures used to test degradation of the formulation. (*See, e.g.*, Exh. 1, '838 patent at col. 23, l. 36 – col. 24, l. 33 (particularly col. 23, ll. 48-50).)

Regarding degradation, the specifications of the Horizon patents clearly support the inclusion of these terms in the claims, stating that one of the features of the claimed invention includes “decreased degradation of diclofenac sodium, which degrades by less than 0.04% over the course of 6 months.” (Exh. 1, '838 patent, col. 5, ll. 50-52.) In this same regard, the specifications disclose that the present invention provides a diclofenac sodium formulation that degrades by less than 1% over the course of 6 months at room temperature. (Exh. 1, '838 patent, col. 9, l. 66 to col. 10, l. 4.)

Example 6 discloses how to determine the extent of degradation, and also discloses that the degradation impurity is “impurity A.”

In this study, samples of the test compositions were placed into plastic screw cap bottles which were sealed and held at 25° C. at 60% humidity for 6 months. After the 6 month storage period, the samples were tested for impurities by high performance liquid chromatography (HPLC). The active agent, diclofenac sodium, was found to elute by HPLC with an elution time of about 11 minutes. It was found that upon 6 months of storage, an impurity, termed “impurity A”, was seen to elute at about 6.6 minutes in varying amounts for the various compositions as shown in Table 13 below.

(Exh. 1, '838 patent, col. 23, ll. 48-58.) Further, one of the headings in Table 13 is “Percent ‘impurity A’ after 6 months of storage (wt/wt).”

A POSA would understand that room temperature refers to 25° C as this is clearly outlined in the specifications. (*See* Walters Decl. ¶ 46.) In view of the specifications, a POSA

would understand that the degradation limitations in the claims are referring to the amount of “impurity A” found in the formulation after 6 months at 25° C at 60% humidity. (*See* Walters Decl. ¶¶ 42-46.) A POSA further would understand that Impurity A was referring to USP Diclofenac Related Compound A RS—an impurity known and described in the literature at the time of the invention. (*See* Walters Decl. ¶¶ 46-54.) To determine diclofenac’s degradation products and the structure of those products, a POSA would look to literature references – including the USP which provides information concerning pharmaceutical ingredients and impurities – available at the relevant time, such as those shown below. (*See* Walters Decl. ¶¶ 47-54.)

- 2003 USP 26
 - The entry for diclofenac sodium in The United States Pharmacopeia 26, (Jan. 1, 2003) identifies USP Diclofenac Related Compound A RS as an impurity for diclofenac sodium. (*See* United States Pharmacopeia 26, (Jan. 1, 2003), pp. 595-596 (Exh. 16, HZNPENN_00038168-HZNPENN_00038169).)
 - The entry for USP Diclofenac Related Compound A RS provides the chemical structure. (*See* United States Pharmacopeia 26, (Jan. 1, 2003), p. 1975 (Exh. 16, at HZNPENN_00038171).)
- 2000 USP 24
 - The entry for diclofenac sodium in The United States Pharmacopeia 24, (Jan. 1, 2000) identifies USP Diclofenac Related Compound A RS as an impurity for diclofenac sodium. (*See* United States Pharmacopeia 24, (Jan. 1, 2000), p. 546 (Exh. 17, at HZNPENN_00038167).)

- The entry for USP Diclofenac Related Compound A RS provides the chemical structure. (*See* United States Pharmacopeia 24, (Jan. 1, 2000), p. 1786 (Exh. 17 at, HZNPENN_00038170).)
- European Pharmacopeia, 5th Edition (2004)
 - The entry for diclofenac sodium in the European Pharmacopeia, 5th Edition (2004) identifies Impurity A and identifies its chemical structure as well. (*See* European Pharmacopeia, 5th Edition (2004), pp. 1420-1422, (Exh. 18, HZNPENN_00038172-HZNPENN_00038176, at HZNPENN_00038174-175)
- European Pharmacopeia, 6th Edition (2005)
 - The entry for diclofenac sodium in the European Pharmacopeia, 6th Edition (2005) identifies Impurity A and identifies its chemical structure as well. (*See* European Pharmacopeia, 6th Edition (2005), pp. 1686-1687, (Exh. 19, HZNPENN_00038177-HZNPENN_00038180, at HZNPENN_00038179-180)

Thus, a POSA, at the time of the invention, would have an understanding of the chemical structure of Impurity A referred to in the patent. (*See* Walters Decl. ¶ 54.)

The evidence above shows that the term is not indefinite and that “the formulation degrades by less than 1% over 6 months” should be construed as one of skill would understand it in view of the claims, the specification and prosecution history: less than 1% of Impurity A (USP Diclofenac Related Compound A RS) present in a formulation sample after the sample was maintained at 25°C and 60% humidity for 6 months.

Defendants allege that the term “the formulation degrades by less than 1% over 6 months” is indefinite. But Defendants cannot meet the exacting burden of proving that this term is “not amenable to construction” or is “insolubly ambiguous.” *Datamize LLC v. Plumtree*

Software, Inc., 417 F.3d 1342, 1347 (Fed. Cir. 2005). When “the meaning of the claim term is discernible ... [it is] sufficiently clear to avoid invalidity on indefiniteness grounds.” *Exxon Res. & Eng’g Co. v. United States*, 265 F.3d 1371, 1375 (Fed Cir. 2001). Moreover, Defendants admit that this term is not indefinite and has a “meaning” via their proposal that this term be construed in accordance with its “plain and ordinary meaning.”

As shown above, the term “the formulation degrades by less than 1% over 6 months” read in light of the specification and the prosecution history informs, with reasonable certainty, those skilled in the art about the scope of the invention.

D. “the topical formulation produces less than 0.1% impurity A after 6 months at 25°C and 60% humidity”

Disputed Claim Term	Claim(s)	Horizon’s Proposed Construction	Defendants’ Proposed Construction
“the topical formulation produces less than 0.1% impurity A after 6 months at 25°C and 60% humidity”	’913 patent: claim 4	Less than 0.1% of Impurity A (USP Diclofenac Related Compound A RS) present in a formulation sample after the sample was maintained at 25°C and 60% humidity for 6 months	This term is indefinite because it does not inform a person of ordinary skill with reasonable certainty of what is claimed. If impurity A is construed to mean USP Diclofenac Related Compound A RS, then the remainder of the term should be given its plain and ordinary meaning.

As shown above in section V.C., the term “the topical formulation produces less than 0.1% impurity A after 6 months at 25°C and 60% humidity” read in light of the specification and the prosecution history informs a POSA about the scope of the invention, is not indefinite, and should be construed as meaning “less than 0.1% of Impurity A (USP Diclofenac Related

Compound A RS) present in a formulation sample after the sample was maintained at 25°C and 60% humidity for 6 months.” (See also Walters Decl. ¶¶ 57-59.)

E. “said diclofenac sodium degrades by less than 0.04% over the course of 6 months”

Disputed Claim Term	Claim(s)	Horizon’s Proposed Construction	Defendants’ Proposed Construction
“said diclofenac sodium degrades by less than 0.04% over the course of 6 months”	’838 patent: claims 7 and 66	Less than 0.04% of Impurity A (USP Diclofenac Related Compound A RS) present in a formulation sample after the sample was maintained at 25°C and 60% humidity for 6 months	This term is indefinite because it does not inform a person of ordinary skill with reasonable certainty of what is claimed. If construed, the term should be given its plain and ordinary meaning.

As shown above in section V.C., the term “said diclofenac sodium degrades by less than 0.04% over the course of 6 months” read in light of the specification and the prosecution history informs a POSA about the scope of the invention, is not indefinite, and should be construed as meaning “less than 0.04% of Impurity A (USP Diclofenac Related Compound A RS) present in a formulation sample after the sample was maintained at 25°C and 60% humidity for 6 months.” (See also Walters Decl. ¶¶ 60-62.)

F. “topical diclofenac preparation”

Disputed Claim Term	Claim(s)	Horizon’s Proposed Construction	Defendants’ Proposed Construction
“topical diclofenac preparation”	’450 patent: claims 1-5, 7, 9-11 and 14-20 ’078 patent: claims 1, 2, 5, 9, 11 and 14	A solution or gel formulation for transdermal administration of diclofenac or its pharmaceutically acceptable salts thereof or its free	a preparation containing diclofenac, or pharmaceutically acceptable salts thereof or its free acid form, that can

	'164 patent: claims 1, 2 and 5-8	acid form as described in the claims	be applied to the skin or mucosa.
	'110 patent: claims 1-28		

Horizon submits that the term “topical diclofenac preparation” should be construed as one of skill would have understood it in view of the claims, the specification and prosecution history: A solution or gel formulation for transdermal administration of diclofenac or its pharmaceutically acceptable salts thereof or its free acid form as described in the claims.

In contrast, Defendants’ construction seeks to broaden the claim to any “preparation ... that can be applied to the skin” in order to aid their obviousness position in this action. Because a POSA would not have understood this term to have the breadth attributed to it by Defendants – to include any “preparation ... that can be applied to the skin” – the Court should reject Defendants’ proposed (and unsupported) construction.

The specifications compel the construction of a topical diclofenac preparation as “a solution or gel formulation for transdermal administration as described herein.” (*See* Exh. 6, ’450 patent, col. 13, ll. 3-6, “a topical diclofenac preparation (e.g., a solution or gel formulation for transdermal administration as described herein).” The specifications state that “diclofenac” includes its pharmaceutically acceptable salts thereof or its free acid form. (*See* Exh. 6, ’450 patent, col. 10, ll. 4-11.) Simply combining these two statements found in the specifications, the term a “topical diclofenac preparation” should be construed as one of skill would have understood it in view of the claims and the specification: “a solution or gel formulation for transdermal administration of diclofenac or its pharmaceutically acceptable salts thereof or its free acid form as described in the claims.” (*See* Walters Decl. ¶¶ 64-68.)

G. “the patient being informed to”

Disputed Claim Term	Claim(s)	Horizon’s Proposed Construction	Defendants’ Proposed Construction
“the patient being informed to”	’110 patent: claims 1-9, 24	The patient is instructed by a medical care worker, either orally, by published material or by demonstration, to perform the steps of the method	The patient is instructed to perform the steps of the method. Alternatively, this term is indefinite because it does not inform a person of ordinary skill with reasonable certainty of what is claimed.

Horizon submits that the term “the patient being informed to” should be construed as one of skill would have understood it in view of the claims, the specification and prosecution history: The patient is instructed by a medical care worker, either orally, by published material or by demonstration, to perform the steps of the method.

The term “patient” is defined in the specifications as “a subject in need of medical treatment.” (Exh. 9, ’110 patent, col. 15, ll. 56-60.) The term “informing” is defined in the specifications as providing instruction in three ways: by published material, orally or by demonstration. (*See* Exh. 9, ’110 patent, col. 15, ll. 21-29.) The definition for “informing” includes “presenting information orally, ... by conversation between a medical care worker and a patient.” (*See* Exh. 9, ’110 patent, col. 15, ll. 21-29.) Accordingly, Horizon’s construction of the phrase “the patient being informed to” is consistent with how one of skill would have understood it in view of the claims, the specification and prosecutions history.

A POSA would have understood that in the context of a subject in need of medical treatment, the patient would have been informed not by any person, but by a medical care

worker, as defined in the specifications. (*See* Walters Decl. ¶ 72; *see also* Exh. 9, '110 patent, col. 15, ll. 36-43.)

Defendants' construction is an attempt to broaden the construction of "the patient being informed to" to include instruction from any source, whether that source (person) is qualified to inform a patient ("a subject in need of medical treatment") or not. Defendants ignore the clear guidance in the specifications, as well as the context of the term in the claims. All of the relevant claims are directed to the treatment of pain in the knee(s) of a patient afflicted with osteoarthritis in the knee(s). As the claim clearly and unambiguously places this method in the context of medical treatment of a suffering patient, it is clear that any instruction to the patient must be by a medical care worker. (*See* Walters Decl. ¶¶ 71-74.)

Alternatively, Defendants argue the term is indefinite. Again, Defendants cannot meet the heavy burden of proving that this term is "not amenable to construction" or is "insolubly ambiguous." *Datamize LLC*, 417 F.3d at 1347. When "the meaning of the claim term is discernible ... [it is] sufficiently clear to avoid invalidity on indefiniteness grounds." *Exxon Res. & Eng'g Co.*, 265 F.3d at 1375. Indeed, Defendants admit their argument is without merit as they provide a construction, though ignoring the obvious medical context of the claims, which is otherwise quite similar to Horizon's construction. For these reasons, Horizon's construction of "the patient being informed to" should be adopted.

H. "the patient carrying-out steps i-iii as informed"

Disputed Claim Term	Claim(s)	Horizon's Proposed Construction	Defendants' Proposed Construction
"the patient carrying-out steps i-iii as informed"	'110 patent: claims 1-9, 24	The patient performs each of steps i-iii as instructed by a medical care	The patient performs each of steps i-iii as instructed.

		worker, either orally, by published material or by demonstration	Alternatively, this term is indefinite because it does not inform a person of ordinary skill with reasonable certainty of what is claimed.
--	--	--	--

For at least the reasons discussed above in section V.G., the term “the patient carrying-out steps i-iii as informed” read in light of the specification and the prosecution history informs a POSA about the scope of the invention, is not indefinite, and should be construed as meaning “the patient performs each of steps i-iii as instructed by a medical care worker, either orally, by published material or by demonstration.” (*See also* Walters Decl. ¶¶ 76-79.)

I. “providing information”

Disputed Claim Term	Claim(s)	Horizon’s Proposed Construction	Defendants’ Proposed Construction
“providing information”	’110 patent: claims 10-11, 18-19, 26	A medical care worker providing instructions, either orally, by published material or by demonstration	Providing instructions. Alternatively, this term is indefinite because it does not inform a person of ordinary skill with reasonable certainty of what is claimed.

For at least the reasons discussed above in section V.G., the term “providing information” read in light of the specification and the prosecution history informs a POSA about the scope of the invention and is definite and should be construed as meaning “a medical care worker providing instructions, either orally, by published material or by demonstration.” (*See also* Walters Decl. ¶¶ 80-83.)

J. “informing the patient to”

Disputed Claim Term	Claim(s)	Horizon’s Proposed Construction	Defendants’ Proposed Construction
“informing the patient to”	’110 patent: claims 12-13, 20-21, 27-28	The patient is instructed by a medical care worker, either orally, by published material or by demonstration, to perform the steps of the method	The patient is instructed to perform the steps of the method. Alternatively, this term is indefinite because it does not inform a person of ordinary skill with reasonable certainty of what is claimed.

For at least the reasons discussed above in section V.G., the term “informing the patient to” read in light of the specification and the prosecution history informs a POSA about the scope of the invention and is definite and should be construed as meaning “the patient is instructed by a medical care worker, either orally, by published material or by demonstration, to perform the steps of the method.” (*See also* Walters Decl. ¶¶ 84-87.)

K. “a greater drying rate”

Disputed Claim Term	Claim(s)	Horizon’s Proposed Construction	Defendants’ Proposed Construction
“a greater drying rate”	’838 patent: claims 1-19, 21-24, 27-33, 35-43, 46-48, 62-69	Wherein a lesser amount (wt) of the claimed formulation remains relative to the amount (wt) of the comparative liquid formulation after 100 mg of both formulations are spread over 10 cm ² area and exposed to ambient	This term is indefinite because it does not inform a person of ordinary skill with reasonable certainty of what is claimed. If construed, “a greater drying rate” requires a lesser amount (wt) of the claimed formulation remains relative to

		conditions over a 24 hour period	the amount (wt) of the comparative liquid formulation after 100 mg of both formulations are spread over 10 cm ² area and exposed to ambient conditions over a time period
--	--	----------------------------------	--

Horizon submits that the term “a greater drying rate” should be construed as one of skill would have understood it in view of the claims, the specification and prosecution history: Wherein a lesser amount (wt) of the claimed formulation remains relative to the amount (wt) of the comparative liquid formulation after 100 mg of both formulations are spread over 10 cm² area and exposed to ambient conditions over a 24 hour period.

In contrast, Defendants allege that this term is indefinite. However, in the absence of its indefiniteness argument, Defendants’ proposed construction is in large part the same as Horizon’s. A POSA would have understood that the term “a greater drying rate” should be construed as shown below. “[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014). Horizon’s construction is consistent with the procedure for measuring drying rate in the specification of the ’838 patent. Defendants, however, ignore the clear instructions in the specification of the ’838 patent for measuring drying rate. Accordingly, Horizon’s construction should be adopted.

The ’838 patent is presumed valid. 35 U.S.C. § 282; *see Microsoft Corp. v. i4i Ltd. P’ship*, 131 S. Ct. 2238, 2242-43 (2011). Defendants must prove invalidity by clear and convincing evidence. *See id.* To prevail on their indefiniteness challenge, Defendants must meet

“an exacting standard,” and prove that a POSA “could not discern the boundaries of the claim.”

Haemonetics Corp. v. Baxter Healthcare Corp., 607 F.3d 776, 783 (Fed. Cir. 2010).

Indefiniteness is a question of law. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir. 2015). “[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014).

Defendants allege that the term “a greater drying rate” is indefinite. But they cannot meet the exacting burden of proving that “a greater drying rate” is “not amenable to construction” or “insolubly ambiguous.” *Datamize LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1347 (Fed. Cir. 2005). Indeed, Defendants have proposed a construction – in essence admitting the term is not indefinite – and undermining any argument that the term is insolubly ambiguous. Further, and in the absence Defendants’ indefiniteness argument, the parties’ proposed constructions are almost identical, and are supported by the specification and the file history. This falls far short of meeting the standard for indefiniteness. When “the meaning of the claim term is discernible ... [it is] sufficiently clear to avoid invalidity on indefiniteness grounds.” *Exxon Res. & Eng’g Co. v. United States*, 265 F.3d 1371, 1375 (Fed Cir. 2001). As shown below, the term “a greater drying rate” read in light of the specification and the prosecution history informs a POSA about the scope of the invention.

The specification of the ’838 patent makes clear that “a greater drying rate” refers to “wherein a lesser amount (wt) of the claimed formulation remains relative to the amount (wt) of the comparative liquid formulation after 100 mg of both formulations are spread over 10 cm² area and exposed to ambient conditions over a 24 hour period.”

The specifications describe the exact process the inventors used to compare the drying times of the claimed formulation relative to the comparative liquid formulation. The specifications state “[t]o compare the drying times more quantitatively, side-by-side comparisons were conducted. To accomplish this, the inventors measured the residual weight of formulations by placing equal amounts (100 mg) of a prior art formulation and compositions of the invention in weighing dishes over 10 cm² areas and weighing the amount remaining over time.” (Exh. 1, ’838 patent, col. 10, ll. 22-27.)

The specifications, in Example 5 of the ’838 patent, provide further detail regarding the comparison of drying time. This example reiterates that “[e]qual amounts (100 mg) of either the comparative liquid formulation solution or diclofenac sodium gel formulations were measured on to plastic weigh dishes and spread over a 10 cm² area, and then left exposed to ambient conditions.” (Exh. 1, ’838 patent, col. 21, ll. 47-51.)

The prosecution history also supports Horizon’s construction in that it provides that the inventive formulations have an unexpectedly faster drying rate than the comparable prior art liquids:

Applicants assert that it is completely unexpected that a gel composition would have a **greater drying rate** (i.e., a **shorter drying period**) as well as greater flux **compared to a comparative liquid composition**. The claimed **faster drying rate** and greater flux allows for a fewer number of doses (i.e., fewer applications of the medicament). In addition, the **faster drying rate** allows for more convenience of use, wherein it is possible to apply other dermal products (e.g., sunscreen) without waiting a long period of time. As such, Applicants are teaching and claiming a transdermal diclofenac sodium gel formulation with high amounts of DMSO, which formulation has an **advantageous drying rate** as well as flux. These are unexpected advantageous properties that the cited art simply does not possess.

(Exh. 20, Amdt. dated July 29, 2010, pages 10-11, ACT-PENN0002927-2947 at ACT-PENN0002936-37.)

In contrast, Applicants teach and claim a gel composition having a **faster drying rate** (i.e., a **shorter drying period**) and greater flux **compared to the liquid composition of Sandborn**. A skilled person would have no expectation of success of preparing a gel formulation and at the same time **increasing the drying rate** and transdermal flux. This is an unexpected and advantageous feature that the cited art simply does not possess. It was totally unexpected that a “gel” would have a **greater drying rate** compared to a “liquid.”

(Exh. 20, Amdt. dated July 29, 2010, page 13, ACT-PENN0002927-2947 at ACT-PENN0002939.)

The specifications and file history support that “a greater drying rate” refers to the comparison of the drying times of the claimed formulation relative to the comparative liquid formulation and make clear that it was unexpected that the inventive formulations would have a greater drying rate compared to the prior art liquids. In other words, in a side-by-side comparison, the inventive formulations would leave less residue than the prior art liquids at a given time under similar conditions.

A POSA would have understood that the “greater drying rate” is referring to the “comparative liquid formulation.” (See Walters Decl. ¶¶ 93-94.) A POSA would have understood that in order to determine whether a formulation had a “greater drying rate” than the comparative liquid formulation, they would perform the process outlined in the patent specification and compare results at 24 hours. (See Walters Decl. ¶ 94.) As the data in Table 12 and Figure 11 demonstrates, a POSA would have understood that the inventors carried this comparison out over a 24 hour period. (See Walters Decl. ¶ 95.) A POSA would have understood that the specifications further demonstrate the 24 hour time period as the relevant benchmark for comparison, stating that by 24 hours, this difference was even more pronounced, and that this surprising result demonstrates that the inventive formulations display superior

drying characteristics as compared to a comparable liquid formulation. (*See* Walters Decl. ¶ 95; *see also* Exh. 1, '838 patent, col. 22, ll. 1-14.)

In the absence of Defendants' indefiniteness argument, the parties' constructions are almost identical and, as shown above, fully supported by the specifications and the file history. The '838 patent clearly instructs a POSA how to determine "a greater drying rate" and this term should be construed to refer to "wherein a lesser amount (wt) of the claimed formulation remains relative to the amount (wt) of the comparative liquid formulation after 100 mg of both formulations are spread over 10 cm² area and exposed to ambient conditions over a 24 hour period."

L. "said drying rate results in a residue of at most 50% of a starting amount after 24 hours"

Disputed Claim Term	Claim(s)	Horizon's Proposed Construction	Defendants' Proposed Construction
"said drying rate results in a residue of at most 50% of a starting amount after 24 hours"	'838 patent: claims 5-6, 64-65	Wherein a lesser amount (wt) of the claimed formulation remains relative to the amount (wt) of the comparative liquid formulation after 100 mg of both formulations are spread over a 10 cm ² area and exposed to ambient conditions over the same time period, and wherein the amount of the claimed formulation remaining after 24 hours of the exposure is no	This term is indefinite because it does not inform a person of ordinary skill with reasonable certainty of what is claimed. If construed, the term should be given its plain and ordinary meaning.

		more than 50 wt.% of the starting amount (wt)	
--	--	---	--

This term, “said drying rate results in a residue of at most 50% of a starting amount after 24 hours,” is related to and refers to the term “a greater drying rate.” For the same reasons as outlined above for “a greater drying rate,” the part of the construction for “wherein a lesser amount (wt) of the claimed formulation remains relative to the amount (wt) of the comparative liquid formulation after 100 mg of both formulations are spread over a 10 cm² area and exposed to ambient conditions over the same time period,” is not indefinite, and the intrinsic evidence demands that the term be construed as outlined in section V.K. (*See also* Walters Decl. ¶¶ 100-101.) For the remainder of the construction, “wherein the amount of the claimed formulation remaining after 24 hours of the exposure is no more than 50 wt% of the starting amount (wt),” the claim itself is clear without more as it states that the residue of the claimed formulation is at most 50% of a starting amount after 24 hours.

Defendants allege that the term “said drying rate results in a residue of at most 50% of a starting amount after 24 hours” is indefinite. However, Defendants cannot meet the exacting burden of proving that “said drying rate results in a residue of at most 50% of a starting amount after 24 hours” is “not amenable to construction” or “insolubly ambiguous.” *Datamize LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1347 (Fed. Cir. 2005). When “the meaning of the claim term is discernible ... [it is] sufficiently clear to avoid invalidity on indefiniteness grounds.” *Exxon Res. & Eng’g Co. v. United States*, 265 F.3d 1371, 1375 (Fed Cir. 2001). Here, the specifications teach how to make the claimed formulations. (*See, e.g.*, Exh. 1, ’838 patent at col. 10, l. 49 - col. 11, l. 5.) The specifications teach specific examples of the claimed formulation. (*See, e.g.*, Exh. 1, ’838 patent at Table 5 – Table 10, Table 12 (Formulation F/14/2), col. 5, ll. 29-45.) The specifications also teach the conditions and method for measuring the drying rate and

residue. (See Exh. 1, '838 patent at e.g., col. 21, l. 45 – col. 23, l. 27 (particularly col. 21, ll. 45-54); see also col. 10, ll. 15-30.) For at least these reasons, a POSA would have understood the claim term “wherein said drying rate results in a residue of at most 50% of a starting amount after 24 hours” as used in the asserted claims. (See Walters Decl. ¶¶ 102-105.) Therefore, the asserted claims are not indefinite because the term “wherein said drying rate results in a residue of at most 50% of a starting amount after 24 hours,” when read in the light of the specifications and with the knowledge in the art, would have reasonably apprised a POSA of the scope of the asserted claims.

M. “as determined by a Franz cell procedure at finite or infinite dosing”

Disputed Claim Term	Claim(s)	Horizon’s Proposed Construction	Defendants’ Proposed Construction
“as determined by a Franz cell procedure at finite or infinite dosing”	'838 patent: claims 1-19, 21-24, 27-33, 35-43, 46-48, 62-69	The Franz cell procedure as described in the '838 patent at col. 13, ll. 1-32 (including the Franz article cited therein)	This term is indefinite because it does not inform a person of ordinary skill with reasonable certainty of what is claimed.

Horizon’s construction is consistent with the procedure for measuring flux in the specification of the '838 patent. Defendants, however, again ignore the clear instructions in the specifications for measuring flux.

The specifications define the term “finite dosing” to “generally include an application of a limited reservoir of an active agent. The reservoir of the active agent is depleted with time leading to a tapering off of the active absorption rate after a maximum absorption rate is reached.” (Exh. 1, '838 patent, col. 7, ll. 18-22.) The specifications define the term “infinite dosing” to “generally include an application of a large reservoir of an active agent. The reservoir

is not significantly depleted with time, thereby providing a long term, continuous steady state of active absorption.” (Exh. 1, ’838 patent, col. 7, ll. 23-27.)

The specifications teach how to make the claimed formulations. (*See, e.g.*, Exh. 1, ’838 patent at col. 10, l. 49 - col. 11, l. 5.) The specifications teach specific examples of the claimed formulation. (*See, e.g.*, Exh. 1, ’838 patent at Table 5 – Table 10, Table 12 (Formulation F/14/2), col. 5, ll. 29-45.) The specifications also teach the parameters and method for using the Franz cell procedure:

Franz diffusion cell experiments were used to analyze diclofenac sodium flux rates of varying gel formulations across a substrate membrane. Franz diffusion cells are a common and well known method for measuring transdermal flux rates. The general Franz cell procedure is described in Franz, T. J., *Percutaneous absorption: on the relevance of in vitro data*. *J Invest Derm*, 64: 1 90-195 (1 975). The following was the methodology used in the present Examples.

Franz cells with a 3 ml receptor well volume were used in conjunction with split thickness cadaver skin (0.015"-0.018", AlloSource). The donor well had an area of $\sim 0.5 \text{ cm}^2$. Receptor wells were filled with isotonic phosphate buffered saline (PBS) doped with 0.01 % sodium azide. The flanges of the Franz cells were coated with vacuum grease to ensure a complete seal and were clamped together with uniform pressure using a pinch clamp (SS # 18 VWR 80073-350). After Franz cells were assembled, the skin was allowed to prehydrate for 45 minutes with PBS. PBS was then removed and an appropriate amount of formulation is added to the skin. Dosing levels varied from 2 mg/cm^2 (considered finite dose) 2 to 200 mg/cm^2 (considered infinite dose). The donor well was then capped to prevent evaporation. Receptor wells of the Franz cells were maintained at 37° C . (temperature on the surface of the skin is $\sim 31^\circ \text{ C}$.) in a stirring dry block with continual agitation via a stir bar. Samples were drawn from the receptor wells at varying time points. Measurements were made in six-fold replicates. The concentration of diclofenac in the samples was analyzed using high performance liquid chromatography. The inventive formulations performed better than the comparator at the limits of finite dosing-finite dosing being a much better predictor of the performance of a formulation in an in vivo situation as opposed to infinite dosing.

(Exh. 1, '838 patent, col. 13, ll. 1-32.) The specifications point to the description of the general Franz cell procedure as described in the prior art. (*See, e.g.*, Exh. 1, '838 patent at col. 13, ll. 5-8.) Furthermore, the specifications clearly state that this is the exact procedure that was used to determine the relative transdermal flux.

Studies were performed to determine the relative transdermal flux of various diclofenac gel formulations of the present invention when compared with a comparative liquid formulation of U.S. Pat. Nos. 4,575,515 and 4,652,557 ("Comparative" in Tables 5-10). Accordingly, the Franz cell procedure described above was used to compare diclofenac flux rates of various diclofenac gel formulations with comparative liquid formulations.

(Exh. 1, '838 patent, col. 16, ll. 50-57; Exh. 21, Amdt. dated January 5, 2010, ACT-PENN0002878-897 at ACT-PENN0002895; Exh. 22, Amdt. dated February 4, 2013, ACT-PENN0007845-958 at ACT-PENN0007857.)

A POSA would have understood to use the methodology outlined in the specifications to determine whether a formulation met the flux limitations of the claims. (*See* Walters Decl. ¶ 111.) This methodology provides sufficient guidance and no other factors, other than those disclosed in the patent specifications, would significantly alter flux measurements. (*See* Walters Decl. ¶ 111.) Furthermore, the measurements are comparative measurements, so as long as the specific conditions are equivalent for each test sample, the listing of specific details and conditions are not actually necessary. (*See* Walters Decl. ¶ 112.) For at least these reasons, a POSA would have understood the claim term "as determined by a Franz cell procedure at finite or infinite dosing" as used in the asserted claims. Therefore, the asserted claims are not indefinite because the term "as determined by a Franz cell procedure at finite or infinite dosing," when read in the light of the specification and with the knowledge in the art, would have reasonably apprised a POSA of the scope of the asserted claims.

Defendants allege that the term “as determined by a Franz cell procedure at finite or infinite dosing” is indefinite. Defendants cannot, however, meet the exacting burden of proving that “as determined by a Franz cell procedure at finite or infinite dosing” is “not amenable to construction” or “insolubly ambiguous.” *Datamize LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1347 (Fed. Cir. 2005). When “the meaning of the claim term is discernible ... [it is] sufficiently clear to avoid invalidity on indefiniteness grounds.” *Exxon Res. & Eng’g Co. v. United States*, 265 F.3d 1371, 1375 (Fed Cir. 2001). As shown above, the term “as determined by a Franz cell procedure at finite or infinite dosing” read in light of the specifications and the prosecution history informs a POSA about the scope of the invention and is, therefore, not indefinite.

N. “hydroxypropyl-cellulose (HY119)”

Disputed Claim Term	Claim(s)	Horizon’s Proposed Construction	Defendants’ Proposed Construction
“Hydroxypropyl-cellulose (HY119)”	’838 patent: claim 63	Hydroxypropyl cellulose, 150-400 centipoise	The specific hydroxypropylcellulose obtained from Spectrum under vendor number HY119 and CAS 9004-64-2.

Horizon submits that the term “Hydroxypropyl-cellulose (HY119)” should be construed as one of skill would understand it in view of the claims, the specification and prosecution history: Hydroxypropyl cellulose, 150-400 centipoise. Horizon’s construction defines the term by its functional feature, 150-400 centipoise. In contrast, Defendants’ construction seeks to limit claim by limiting the term to its manufacturer, Spectrum Chemicals and Laboratory Products, Inc. Because a POSA would not have limited this claim to one particular manufacturer, the Court should reject Defendants’ proposed construction.

The language of claim 63 establishes that the thickening agent is hydroxypropylcellulose (HY119). Hydroxypropylcellulose (HY119) is listed in the materials in Table 1 of the '838 patent having the source Spectrum, vendor # HY119, and CAS 9004-64-2.

A skilled person in the art at the time of the invention would not have understood the term “hydroxypropylcellulose (HY119)” to be limited to hydroxypropylcellulose purchased from a particular vendor. (*See* Walters Decl. ¶ 118.) A POSA would have looked to the information listed on the Spectrum Chemical Webpage and find that it identifies the product HY119 as “hydroxypropyl cellulose, 150-400 cps.” (*See* Walters Decl. ¶ 118.) A POSA would understand that hydroxypropylcellulose is available in many grades and viscosities and that HY119 refers to “hydroxypropylcellulose, 150-400 centipoise” and would not require that the specific hydroxypropylcellulose required must be obtained from Spectrum Chemicals. (*See* Walters Decl. ¶ 118.)

Defendants’ proposed construction attempts to improperly limit the definition of “hydroxypropylcellulose (HY119)” to just one vendor, Spectrum Chemicals. But the intrinsic record offers no legitimate basis to depart from the meaning that “hydroxypropylcellulose (HY119)” would have to those of skill in the art. Indeed, Defendants’ proposed construction runs contrary to how a POSA would understand “hydroxypropylcellulose (HY119).” Consequently, “hydroxypropylcellulose (HY119)” should not be limited to just one vendor, but should be given its proper meaning—hydroxypropylcellulose, 150-400 centipoise.

VI. CONCLUSION

For the foregoing reasons, Horizon respectfully requests that the Court adopt Horizon’s proposed constructions of the disputed claim terms.

Date: November 2, 2015

s/ John E. Flaherty
John E. Flaherty
Ravin R. Patel
McCARTER & ENGLISH LLP
Four Gateway Center
100 Mulberry St.
Newark, NJ 07102
Telephone: (973) 622-4444

Attorneys for Plaintiffs Horizon Pharma Ireland Limited, HZNP Limited and Horizon Pharma USA, Inc.

Robert F. Green
Christopher T. Griffith
Caryn C. Borg-Breen
Jessica M. Tyrus
Benjamin D. Witte
GREEN GRIFFITH & BORG-BREEN LLP
NBC Tower, Suite 3100
455 North Cityfront Plaza Drive
Chicago, Illinois 60611
Telephone: (312) 883-8000

Dennis A. Bennett
GLOBAL PATENT GROUP, LLC
1005 North Warson Road, Suite 404
St. Louis, Missouri 63132
Telephone: (314) 812-8020

Of Counsel for Plaintiffs Horizon Pharma Ireland Limited, HZNP Limited and Horizon Pharma USA, Inc.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that true and correct copies of PLAINTIFFS' OPENING CLAIM CONSTRUCTION BRIEF were caused to be served on November 2, 2015, via email upon counsel of record.

Date: November 2, 2015

s/ John E. Flaherty